

REMARKS

Applicants have carefully considered the matters raised by the Examiner in the outstanding Office Action but remain of the opinion that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the above amendments to the claims and the following remarks.

In the amendments to the claims, claims 1-6 have been cancelled. Claim 7 has been amended to recite that the dried agglomerated modified cyclodextrin product is porous, flake-shaped and uncomplexed. Support for these amendments can be found on page 7, line 1, where it states that the cyclodextrin is uncomplexed; page 10, first full paragraph, where it states that the product has a shape of a flake; and page 10, second full paragraph, where it states that the product is porous. Claim 12 has also been amended herein to recite that the dried agglomerated modified cyclodextrin is porous, flake-shaped and uncomplexed. Claim 12 has further been amended to add the limitations of claim 14 and claim 14 has been cancelled. Because of the cancellation of claim 14, claims 16 and 18 have been amended to be dependent upon claim 12. It is submitted that no new matter has been entered by way of these amendments. Thus, claims 7-13 and 15-18 are currently under prosecution.

One of the novel features of the present invention is the discovery that by drying an aqueous solution of uncomplexed modified cyclodextrin on a double-drum dryer, that a porous, flake-shaped agglomerate of the uncomplexed modified cyclodextrin is formed. This dried agglomerate has superior properties compared to the conventional spray dried product. First, the present invention does not have the dusting problems associated with a spray-dried product. Second, the product of the present invention has greatly improved dissolving properties which allow the product of the present invention to dissolve more rapidly than the spray-dried product. It has also been found that the product of the present invention has physical characteristics which distinguish it from a spray-dried product. Those physical characteristics include the fact that it is flake-shaped, it is porous, and that it has a larger particle size than the spray dried product. These attributes of the present invention are brought out in the second full paragraph on page 4 and are also highlighted by the examples therein. In example 5, a comparison is made between spray dried product and the product of the present invention. It can be seen that the product of the present invention has generally a larger particle size and that the dissolution rate of the product of the present invention is substantially smaller than the dissolution rate of the spray dried product. In fact, the product of the present invention dissolves in water some 3 to 10 times faster than the spray dried product. These facts can be clearly seen from the

table which is at the top of page 14. The physical characteristics are the flake-shaped and porous nature of the product of the present invention compared to a spray dried product as illustrated in example 6 and shown in the figures. As discussed in the fourth paragraph on page 15, the samples of the present invention were flake-shaped as shown in Figs. 2-6 while the spray dried product was bead like in nature as shown in Figs. 6. Also, as brought out by the figures, it was seen that the product of the present invention was porous in nature. This is contrast to the spray dried product which has a non porous structure as discussed in the second full paragraph on page 10.

As noted above, the two independent claims, claim 7 and 12, have been amended herein to highlight the fact that the product of the present invention is a porous flake-shaped uncomplexed agglomerated modified cyclodextrin and that the product is made by the specific process of using a double drum dryer. It is submitted that the references cited by the Examiner do not teach nor suggest these aspects of the present invention.

Claims 1-6 had been rejected as being unpatentable over a combination of Shah and Walsh. Claims 1-6 have been cancelled herein.

Claims 7-11 had been rejected as being unpatentable over a combination of Shah, Walsh and Giacobello; while claims 12-18 had been rejected as being unpatentable over a combination of Majid and Shah. None of these references taken alone or in combination teach or suggest that a dried porous flake shaped uncomplexed agglomerate modified cyclodextrin can be formed using a double drum dryer. Specifically, Shah teaches the formation of a modified cyclodextrin. It also teaches that the product can be isolated by any suitable drying technique to include spray drying or vacuum drying. Shah does not teach nor suggest that by the use of a double dryer a porous flake shaped uncomplexed agglomerate of modified cyclodextrin can be formed. Thus, it is submitted that one of skill in the art when viewing Shah would not be led to the product of the present invention nor the process to make the product of the present invention as recited in the claims currently under prosecution.

Walsh does not aid Shah in its missing elements. Walsh teaches double drum dryers can be used to form a dried product from a bean paste. Walsh teaches that the product from the double drum dryer is a film, see column 6, line 15. Walsh does go on to teach that this film can be broken into flakes of different sizes, see column 6, line 35, however, Walsh teaches that size can be varied and does not specifically teach that the product produced by its process is a porous one which has the specific size as recited in

claims 7 and 12, namely particle size distribution of 90% or more by weight less than or equal to 200 microns and about 50% or more by weight greater than or equal to 20 microns. It may be true that it would be obvious to try based on a combination of Shah ad Walsh to make the product of the present invention, however, the test is not whether it is obvious to try to produce the product of the present invention, but whether the product of the present invention would, in fact, occur if one were to combine the two references. It is submitted that a combination of Shah and Walsh do not lead one of skill in the art to presume that they would produce a porous flake shaped uncomplexed agglomerated modified cyclodextrin which has the specific particle size distribution as recited in the claims herein.

Giacobello has been cited to teach that a drum dryer produces an agglomerated product. Although this is true, it is submitted that the addition of Giacobello to Walsh and Shah still does not lead one of skill in the art to presume that the use of the double dryer can be used to produce a porous flake shaped uncomplexed agglomerated modified cyclodextrin with the specific particle distribution as recited in the claims. Again, it may be obvious to try but it is submitted that it is not obvious to one of skill in the art that such a product will, in fact, be formed.

The final reference, Majid, is directed to forming agglomerates from cyclodextrin complexes. These agglomerates are formed in aqueous phase and then are dried. There is nothing in Majid which would lead one of skill in the art to believe that a slurry of unmodified cyclodextrin when dried on a double drum dryer would form a porous flake shaped uncomplexed agglomerated modified cyclodextrin. It should be pointed out that the cyclodextrin which is used in Majid is unmodified. Specifically, the Examiner will note that each one of the examples uses beta-cyclodextrin. The use of the term beta-cyclodextrin means that the cyclodextrin has not been modified. If it were modified, it would be referred to as modified beta-cyclodextrin. Thus, it is submitted that Majid does not lead one of skill in the art to presume that drying a slurry of uncomplexed modified cyclodextrin on a drum dryer would result in a porous flake shaped uncomplexed agglomerated modified cyclodextrin as recited in the claims herein. Heretofore, cyclodextrins that are made on a commercial scale are typically spray dried. Such spray dried products have a problem due to their dusting and the fact that they are hard to dissolve. Applicants have solved the problem by use of the double drum dryer and have discovered that the process forms a product which was not expected, namely, a porous flake shaped agglomerate of modified cyclodextrin.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and such action is respectfully requested. Should any fees or extensions of time be necessary in order to maintain this application in pending condition, appropriate requests are hereby made and authorization given to debit account #02-2275.

Respectfully submitted,

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